



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

JAN - 9 2002

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Ms. Wina Tran  
President  
Solstice Medicine Company  
1043 Cesar E. Chavez Avenue  
Los Angeles, California 90033

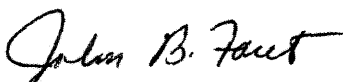
Dear Ms. Tran:

This is in response to your letter of November 26, 2001 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that Solstice Medicine Company intends to market the product "Ryukakusan Herbal Candy" as a dietary supplement.

The product "Ryukakusan Herbal Candy" is not a dietary supplement within the meaning of section 201(ff) of the act. The product is a conventional food because it is represented as a candy, which is a term of identity that describes a conventional food. Section 201(ff)(2)(B) of the act states, in part, that the term dietary supplement means a product that "is not represented for use as a conventional food." Therefore, claims on the label or in the labeling for this product are not subject to section 403(r)(6) of the act and this product may not be marketed as a dietary supplement, but instead, is subject to the requirements that apply to conventional foods.

Please contact us if we may be of further assistance.

Sincerely yours,

  
John B. Foret

Director  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Los Angeles District, Compliance Office, HFR-PA240

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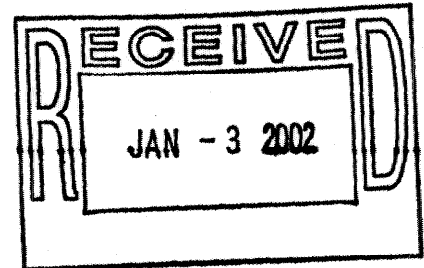
# SOLSTICE MEDICINE COMPANY

1043 CESAR E. CHAVEZ AVE., LOS ANGELES, CA 90033 U. S. A.  
TEL: 323-221-8180 FAX: 323-221-2448 WWW.SOSUSACO.COM

November 26, 2001

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St., S.W.  
Washington, DC 20204

18772



RE: Dietary Supplement Statement of Support Notification

To Whom It May Concern:

SOLSTICE MEDICINE COMPANY, 1043 Cesar E. Chavez Avenue, Los Angeles, CA 90033, who is the distributor of the following dietary supplement product, intends to make the following statement of support:

"Supports the health of the respiratory system and refreshes at the same time. This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

This claim is being made for:  
RYUKAKUSAN HERBAL CANDY

which is contained in:  
RYUKAKUSAN HERBAL CANDY

This submission is being made in compliance with 21 CFR § 101.93.

The undersigned is an authorized representative of the SOLSTICE MEDICINE COMPANY and certifies that the information contained in this notice is complete and accurate, and that SOLSTICE MEDICINE COMPANY has substantiation that the above statement is truthful and not misleading.

Wina Tran  
President